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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,302	12/22/2005	Maria Torpo	P05,0367	3792

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EXAMINER	
BEHRINGER, LUTHER G	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
05/12/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,302	TORPO ET AL.	
	Examiner	Art Unit	
	Luther G. Behringer	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the communication received on 03/15/2010 concerning application no. 10/562302 filed on 12/22/2005.

Response to Arguments

2. Applicant's arguments filed 03/15/2010 have been fully considered but they are not persuasive. Applicant contends that Rosenberg is solely directed to congestive heart failure therapy and does not provide any teaching for the detection of diastolic heart failure. To the contrary, Rosenberg is almost exclusively directed to diastolic monitors of cardiac performance, *EDV, ventricular wall stress, etc.* Failing to specifically name his treatment as pertaining to Diastolic Heart Failure (DHF) does not mitigate the fact that Rosenberg is treating DHF.

3. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., early detection of DHF) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claim(s) 27 – 28 and 47 – 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Rosenberg (US 6,314,322)** (cited previously).

With regard to **claim(s) 27 and 48,** Rosenberg discloses a method and an implantable medical apparatus for detecting diastolic heart failure (DHF) comprising: a sensor adapted to interact with a heart to obtain information associated with functioning of the heart, **24** (Fig. 1); and a DHF determining device supplied with said information that detects a DHF state of the heart from said information, *calculate cardiac cycle interval* **212** and determining that said DHF state exists, and emitting an output signal indicating said DHF state, *adjust anticipated cardiac cycle interval* **222** (Fig. 4) when said time duration exceeds an upper limit value or is below a lower limit value (Col. 8, ll. 52 – 65), but fails to disclose extracting from said information a time duration of only a predetermined phase of diastole of the heart.

6. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the calculation of the cardiac cycle interval as taught by Rosenberg, to reflect diastolic information, such as the T-wave, since it was known in the art that diastolic information is used to provide indicia of cardiac performance parameters for further therapy delivery. In the instant case, the examiner is citing Corbucci (US 2002/0151938; [0041]) as one example.

Regarding **claim(s) 28 and 49,** Rosenberg discloses wherein said DHF determining device comprises a comparator that compares said time duration with an upper limit value and a lower limit value to obtain a comparison result, said comparison result being indicative of said DHF state (Fig. 4; Col. 8, ll. 52 – 65).

Regarding **claim 47,** Rosenberg discloses an implantable cardiac pacemaker comprising: a pulse generator that emits stimulation pulses (Col. 8, ll. 48 – 50); an electrode system, **34**, adapted to interact with the heart of a subject to deliver said stimulation pulses to the heart in a pacing therapy regimen, a sensor adapted to interact with a heart to obtain information associated with functioning of the heart, **24**, and a DHF determining device supplied with said information that detects a DHF state of the heart from said information by determining, as a DHF parameter, a time duration, of a predetermined phase of diastole of the heart, *sensor controller* **26**; and a control unit, *diastolic monitor* **30**, connected to said DHF determining device and to said pulse generator, said control device controlling said pulse generator to modify said pacing therapy regimen dependent on said DHF parameter (Figs. 1 & 4; Col. 8, ll. 31 – 65).

7. Claim(s) 29 – 43 and 50 – 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Rosenberg (US 6,314,322)** in view of **Salo et al. (US 5,584,868, herein Salo)** (both cited previously).

With regard to **claim(s) 29 and 50,** Rosenberg fails to discloses wherein said DHF determining device comprises a calculating unit that calculates, from said information from said sensor, said time duration, as a time from an occurrence of peak blood flow velocity through the mitral valve of the heart to a time of occurrence of zero blood flow velocity through the mitral valve of the heart.

8. However, Salo teaches diagnostic procedures involving adapting the AV interval of a pacemaker based on mitral blood flow (Col. 3, ll. 8 – 26). A person of ordinary skill

in the art at the time of the invention would have found it obvious to use the known cardiac health diagnosis techniques to achieve the predictable result of improved detection of diastolic failure.

Regarding **claim(s) 30 and 51,** Rosenberg in view of Salo disclose wherein said calculating unit determines said time duration by extrapolating said mitral blood flow velocity to zero, if an actual occurrence of zero blood flow velocity through the mitral valve does not occur before an atrial contraction of the heart (Salo: Col. 3, ll. 8 – 12).

With regard to **claim(s) 31 and 52,** Rosenberg in view of Salo inherently discloses wherein said calculating unit extrapolates the blood flow velocity to zero by determining a time derivative of blood flow velocity through the mitral valve shortly after said occurrence of said peak blood flow velocity through the mitral valve (Salo: Col. 3, ll. 8 – 12).

Regarding **claim(s) 32 and 53,** Rosenberg in view of Salo discloses wherein said sensor senses an IEGM signal from the heart (Salo: Col. 4, ll. 4 – 13), and wherein said calculating unit calculates the time of occurrence of said peak blood flow velocity through the mitral valve to the time of occurrence of zero blood flow velocity through the mitral valve from said IEGM (Salo: Col. 2, ll. 54 – 58; Col. 3, ll. 8 – 12).

With regard to **claim(s) 33 and 54,** Rosenberg in view of Salo discloses wherein said sensor is an impedance sensor that senses an impedance of the heart and wherein said calculating unit calculates the time from the occurrence of said peak blood flow velocity through the mitral valve to zero blood flow velocity through the mitral valve from said impedance (Salo: Col. 2, ll. 54 – 58; Col. 3, ll. 8 – 12).

Regarding **claim(s) 36 and 57,** Rosenberg in view of Salo discloses wherein said DHF determining device comprises a calculating unit that calculates, as said time duration, an isovolumic relaxation time (IVRT) from said information from said sensor, *inherent to the AV interval* (Salo: Col. 3, ll. 16 – 27).

With regard to **claim(s) 37 and 58,** Rosenberg in view of Salo discloses wherein said sensor detects an IEGM from the heart (Rosenberg: Col. 9, ll. 29 – 33), and inherently discloses wherein said calculating unit determines said IVRT from said IEGM (Salo: Col. 3, ll. 16 – 27).

Regarding **claim(s) 38 and 59,** Rosenberg in view of Salo discloses wherein said sensor is an impedance sensor that measures an impedance of the heart (Salo: Col. 2, ll. 54 – 58), and wherein said calculating unit calculates said IVRT from said impedance, *inherent to the AV interval* (Salo: Col. 3, ll. 16 – 27).

With regard to **claim(s) 41 and 62,** Rosenberg in view of Salo inherently discloses wherein said DHF determining device determines said time duration, respectively at predetermined time intervals, thereby obtaining a plurality of time durations and comprises a memory in which said plurality of time durations are stored, (Salo: Col. 4, ll. 21 – 24).

Regarding **claim 42,** Rosenberg in view of Salo discloses wherein said DHF determining device determines said time duration respectively at a plurality of predetermined time intervals (Salo: Col. 3, ll. 16 – 27), and comprises a comparator, (Rosenberg: Fig. 4; Col. 8, ll. 52 – 65), capable of comparing each of said time durations to an upper limit value to identify a first plurality of time durations above said

upper limit value and respective first magnitudes of respective deviations of said first plurality of time durations from said upper limit value, and a second plurality of time durations below said lower limit value and second magnitudes of deviations of said second plurality of time durations from said lower limit value, and comprises a memory in which said first plurality of time durations, said first magnitudes, said second plurality of time durations, and said second magnitudes are stored (Salo: Col. 4, ll. 21 – 24).

With regard to **claim(s) 43 and 63,** Rosenberg in view of Salo discloses wherein said DHF determining device determines said time duration at a plurality of different times (Salo: Col. 3, ll. 16 – 27), and determines changes in the respective time durations determined at said different times, and comprises a memory in which said changes are stored (Salo: Col. 4, ll. 21 – 24).

With regard to **claim(s) 34, 35, 39, 40, 55, 56, 60 and 61,** Rosenberg in view of Salo discloses utilizing an acoustic sensor or accelerometer to determine a diastolic performance parameter upon which the blood flow velocity is based (Rosenberg: Col. 2, ll. 54 – 59).

9. Claim(s) 44 – 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Rosenberg (US 6,314,322)** in view of **Salo et al. (US 5,584,868, herein Salo)**. in view of **Paul et al. (US 5,814,088, herein Paul)** (cited previously).

Regarding **claim(s) 44 – 46,** Rosenberg in view of Salo discloses all of the limitations as discloses above, but fails to disclose an alerting unit that emits a humanly perceptible alert.

However, Paul discloses an alerting unit that emits a humanly perceptible alert (Col. 2, ll. 13 – 32).

10. A person of ordinary skill in the art, upon reading the reference, would have recognized the desirability of utilizing an alerting unit to achieve notification of a patient of an alert situation. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify Rosenberg in view of Salo to include an alerting unit as taught by Paul, since notifying a patient of a problem can aid in the correction of that issue and potentially improve the patient's quality of life.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luther G. Behringer whose telephone number is (571)270-3868. The examiner can normally be reached on Mon - Thurs 9:00 - 6:30; 2nd Friday 9:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/Luther G Behringer/
Examiner, Art Unit 3766